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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/696,729

10/29/2003

Scott Freeberg

279.652US1

6340

21186

7590

08/11/2009

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EXAMINER

HOLMES, REX R

ART UNIT

PAPER NUMBER

3762

NOTIFICATION DATE

DELIVERY MODE

08/11/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

uspto@slwip.com

request@slwip.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/696,729	<b>Applicant(s)</b> FREEBERG, SCOTT	
	<b>Examiner</b> REX HOLMES	<b>Art Unit</b> 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 06 April 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-7,9,11-37 and 46-55 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7,9,11-37 and 46-55 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Election/Restrictions*

1. Claims 38, 42 and 45 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 4/6/09.
2. Applicant's election without traverse of Group 1 in the reply filed on 4/6/09 is acknowledged.

### *Claim Rejections - 35 USC § 103*

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1-3, 14-16 and 29-32 are rejected under 35 U.S.C. 103(a) as obvious over Daum et al. (U.S. Pat. 7,101,339 hereinafter "Daum") in view of Park et al. (U.S. Pat. 6,928,324 hereinafter "Park").

6. The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

7. Regarding claims 1-3, 14, 16 and 29-32, Daum discloses a system that includes a current generator (e.g. Col. 2, l. 1), multiple chamber lead placement (e.g. Col. 2, ll. 53-54) of paired electrode leads (e.g. Col. 2, l. 64), a processor adapted to compare impedances and get respiration signals and to monitor the first, second, and possibly third signal (e.g. Col. 1, l. 67 & Col. 2, ll. 3-11 & 61-67; Col. 4, ll. 1-21; Col. 5, ll. 40-43), a filter to determine frequencies in the ventilation band (e.g. Col. 5, ll. 34-36), a therapy output to provide a pacing pulse (e.g. "170"; Col. 1, ll. 15-19; Col. 4, ll. 20-21), a generated ventilation signal (e.g. Col. 2, ll. 3-11). Daum further discloses that stimulators utilize the respiration signals to synchronize the stimulation therapy with the respiration cycle to improve efficiency and performance (Col. 1, ll. 15-19).

8. Regarding claim 15, the system of Daum provides for both left and right heart stimulation and impedance sensing, and thus is inherently creating a transthoracic current field (e.g. Col. 2, ll. 50-67; Col. 3, line 61 to Col. 4, line 12).

9. Regarding claims 1-3, 14-16 and 29-32, Daum discloses that it extracts respiratory signals out of impedance signals and compares the respiration signals to one another but fails to expressly state that those respiratory signals are rate signals. However, Park discloses that thoracic impedance is proportional to ventilation rate (Col. 15, ll. 27-34; Col. 21, ll. 30-43). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Daum, with ventilation rates instead of respiratory impedance signals as taught by Park, since such a modification would provide the predictable results of extracting the proportional ventilation rates out of impedance measurements to provide the predictable results of using other well known respiratory information such as ventilation rates to determine the respiration rate of the patient.

***Claim Rejections - 35 USC § 103***

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 4-6, 9, 11, 13, 19-20, 25-26, 28, 33-34, 46 and 52 are rejected under 35 U.S.C. 103(a) as being obvious over Daum in view of Park as applied to claims 1-3, 14-16 and 29-32 above, and further in view of Andersson et al. (U.S. Pub. 2002/0095189 hereinafter "Andersson").

13. Regarding claims 4-6, 9, 11, 13, 19-20, 25-26, 28, 33-34, 46 and 52, Daum in view of Park discloses the claimed invention including that the respiration signal is used to control stimulation in some devices except for explicitly stating that the respiration signal is used to control the stimulation in the disclosed system. However, Andersson teaches that it is known to use respiration signals to control the stimulation as set forth in (e.g. Abstract, ¶¶ 9, 33, 36 and Claim 1) to provide a demand stimulation based on the workload of the patient. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system that monitors respiration signals as taught by Daum in view of Park, with controlling of the stimulation therapy by the respiration signal as taught by Andersson, since such a modification would provide the predictable results of controlling the implantable device with the respiration signals for providing increase and more accurate stimulation control based on the patient's breathing/workload.

14. Claims 7, 17-18, 21-24, 35-37 and 53-55 are rejected under 35 U.S.C. 103(a) as being obvious over Daum in view of Park as applied to claims 1-3, 14-16 and 29-32 above, and further in view of Hine et al. (U.S. Pat. 7,142,919 hereinafter "Hine").

15. Daum in view of Park discloses the claimed invention as discussed in detail but fails to disclose an impedance monitoring system that includes an activity sensor.

However, Hine discloses a lead system that utilizes impedance, transthoracic impedance, and acceleration in variable pacing (e.g. Col. 6, ll. 1-67). Hine further discloses the use of two accelerometers with intersecting axis's (e.g. Col. 23, ll. 43-56; Col. 26, ll. 15-29). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the impedance monitoring system as taught by Daum in view of Park, with the impedance and acceleration system as taught by Hine, since such a modification would provide the predictable results of an impedance system with more accurate way to determine activity for providing improved pacing during physical activity.

16. Claims 12, 27 and 47-51 are rejected under 35 U.S.C. 103(a) as being obvious over Daum in view of Park in view of Andersson as applied to claims 4-6, 9, 11, 13, 19-20, 25-26, 28, 33-34, 46 and 52 above, and further in view of Hine et al. (U.S. Pat. 7,142,919 hereinafter "Hine").

17. Daum in view of Park in view of Andersson discloses the claimed invention as discussed in detail but fails to disclose an impedance monitoring system that includes an activity sensor. However, Hine discloses a lead system that utilizes impedance, transthoracic impedance, and acceleration in variable pacing (e.g. Col. 6, ll. 1-67). Hine, further discloses the use of two accelerometers with intersecting axis's (e.g. Col. 23, ll. 43-56; Col. 26, ll. 15-29). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the impedance monitoring system as

taught by Daum in view of Park in view of Andersson, with the impedance and acceleration system as taught by Hine, since such a modification would provide the predictable results of an impedance system with more accurate way to determine activity for providing improved pacing during physical activity.

### ***Response to Arguments***

18. Applicant's arguments with respect to claims 1-7, 9, 11-37, 39-40, 43-44 and 47-55 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

19. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Park et al. (U.S. Pat. 6,928,324).- Discloses that thoracic impedance is proportional to ventilation rate (Col. 15, ll. 27-34; Col. 21, ll. 30-43). U.S. Pat. No. 4,901,725 issued to Nappholz et al., U.S. Pat. No. 4,596,251 issued to Plicchi et al., U.S. Pat. No. 5,562,712 issued to Steinhaus et al., or U.S. Pat. No. 5,562,711 issued to Yerich et al. Methods for measuring intra-thoracic impedance measurements used for determining respiration rate and minute ventilation have been proposed for use in monitoring for pulmonary congestion/edema based on evaluation of respiration rate.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to REX HOLMES whose telephone number is (571)272-8827. The examiner can normally be reached on M-F 8:00 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Art Unit: 3762

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/R. H./  
Examiner, Art Unit 3762

/George R Evanisko/  
Primary Examiner, Art Unit 3762